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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNTIED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

HYGIA HEALTH SERVICES, INC.,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No.: 2:06-CV-4798-IPJ
	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

Pending before the court is the summary judgment motion of plaintiff Hygia Health Services, Inc., ("Hygia") (doc. 9). The motion was filed with a supporting brief (doc. 10) and evidentiary materials (doc. 11). Also pending before the court is the summary judgment motion filed by the defendant, the United States Food and Drug Administration ("the FDA") (doc. 14). The FDA's summary judgment motion was filed with a supporting brief (doc. 16) and evidentiary materials (doc. 15). Hygia filed a response in oposition to the FDA's motion (doc. 18) and supplemental evidentiary materials (doc. 19). The FDA filed a reply in support of its motion for summary judgment (doc. 22). The FDA also filed a motion for leave to file a supplemental declaration in support of its motion for summary judgment (doc. 21) to which the Hygia filed a response in opposition (doc. 25).

FACTUAL BACKGROUND

The material facts of this case are undisputed. Hygia is a corporation that reprocesses single-use medical devices for hospitals. Comas Decl. at ¶ 2. Medical

devices are regulated under the Federal Food, Drug, and Cosmetics Act, *See* 21 U.S.C. § 301 et seq., and under federal regulations. During January and February 2005, approximately fifteen to twenty representatives of Alliance Medical Corporation ("Alliance") visited Hygia's facility in Birmingham in furtherance of a potential business relationship. Supplemental Comas Decl. at ¶ 2. At the time Alliance visited Hygia's facility, Alliance also was in the business of reprocessing single-use medical devices. Spears Decl. at ¶ 5. Hygia and Alliance entered into a non-disclosure agreement regarding the potential business relationship. Supplemental Comas Decl. at ¶ 2.

After Alliance visited Hygia's facility, the FDA conducted an inspection of Hygia's facility in May 2005. *Id.* at ¶ 3. The FDA typically inspects Hygia's facility once every two to three years. Comas Decl. at ¶ 3. After the inspection was completed, the FDA informed Hygia in an Establishment Inspection Report (EIR) that no deviations from quality system medical device regulations were found and no objectionable conditions were noted. Supplemental Comas Decl. at ¶ 3.

In 2005 Larry D. Spears was the Deputy Director for Regulatory Affairs in the FDA's Center for Devices and Radiological Health (CDRH). Spears Decl. at ¶ 1. CDRH is the component of the FDA responsible for ensuring the safety and effectiveness of medical devices. *Id.* at ¶ 2. In 2005, Spears received a phone call from an Alliance employee ("the source employee"). *Id.* at ¶ 5. During the phone conversation, the source employee informed Spears that he or she had obtained some "disturbing" information regarding Hygia's medical device quality systems, and

Spears expressed an interest in the information. *Id.* at ¶ 5-6. The source employee requested that the information be kept confidential, and Spears assured the source employee that the information would be kept confidential. *Id.* at ¶ 6. The source employee also told Spears that "management clearence" would be needed before he or she could provide the information to the FDA. *Id.*

Before the source employee provided the information, he or she called Spears again to request that the information regarding Hygia be kept confidential, and Spears told the source employee that the information would be kept confidential. *Id.* at ¶ 7. On February 28, 2005, the source employee sent Spears an email with the subject line "Hygia Trip Report," and the source employee attached a document ("the Alliance Report") to the email. *Id.* at ¶ 8. The Alliance Report is a memorandum from one Alliance employee to another that sets out Alliance's observations and concerns about Hygia's quality systems. *Id.* at ¶ 9. The Alliance Report reveals the names of two Alliance employees including the name of the source employee. *Id.* In the e-mail, the source employee again requested that the information be kept confidential. *Id.* at ¶ 8.

Based on the Alliance Report, Spears had concerns regarding whether Hygia was complying with FDA regulations, and he initiated "internal agency deliberations" regarding the contents of the Alliance Report. *Id.* at ¶ 10. The FDA responded by issuing an assignment to its New Orleans district office to conduct a "follow-up quality systems inspection" of the Hygia facility. *Id.* On March 13-17, 2006, the FDA inspected the Hygia facility. Comas Decl. at ¶ 3; Spears Decl. at ¶ 10. The

March 2006 inspection was a departure from the FDA's typical practice of inspecting the Hygia facility once every two to three years given that the FDA had conducted an inspection of the Hygia facility ten months prior. Comas Decl. at ¶ 3. The FDA advised Hygia that the inspection was being conducted "based on information received from industry." Comas Decl. at ¶ 3; Def.'s Ex. 2.

After the March 2006 inspection, the FDA sent Hygia a copy of an EIR regarding the inspection. Comas Decl. at ¶ 5, Attach. 2.[1] On page 27 of the EIR, the FDA noted that the EIR included following attachments: (1) Hygia Inspectional Report by Steven E. Turtil, Biologist, CDRH/ODE ("the Turtil Report") and (2) the Alliance Medical Corporation Trip Reported, dated 2/28/05 to FDA. *Id.* It is undisputed that the second attachment to the EIR refers to the Alliance Report that was emailed to Spears by the source employee. The FDA did not provide Hygia with these attachments. Compl. at ¶ 9.

In a letter dated July 11, 2006, Hygia submitted a request to the FDA under the Freedom of Information Act ("FOIA"), for the Turtil Report and the Alliance Report. Comas Decl. at ¶ 7, Attach. 4. On August 21, 2006, the FDA provided a partial response to the request. Comas Decl. at ¶ 8, Attach. 5. In the partial response, the

[1]The first page of the EIR contains a summary of the inspection findings. The report states that there were "noted deviations from the medical device quality system good manufacturing practice (QS/GMP) regulations" and it listed specific deficiencies. Def.'s Ex. 2. The EIR also stated that, in general, the inspection revealed that "the firm's written procedures were vague and/or lacked detail ..." *Id.* Although the FDA found some problems with written procedures, Steven Turtil, who conducted the inspection along with Carolyn Blaney, concluded that "the major concerns expressed prior to this inspection have either been adequately addressed, or were not relevant concerns to begin with." Comas Decl. at ¶ 4, Attach. 1 at p. 5.

FDA released part of the Turtil Report. *Id*.

Between August 29 and September 11, 2006, Scott Comas, chief executive officer of Hygia, contacted Larry D. Sadler, the FOIA Denials and Appeals Officer by telephone. Sadler Decl. at ¶¶ 2, 6. Sadler was responsible for determining whether the Alliance Report was exempt from disclosure under FOIA. *Id.* at ¶ 5. Sadler indicated to Comas that the FDA was considering denying Hygia's request for the Alliance Report. *Id.* at ¶ 6. Comas told Sadler the following information: Alliance had considered purchasing Hygia, and Hygia had permitted Alliance personnel into its facility to conduct an inspection; shortly after Alliance employees inspected the Hygia facility, the FDA conducted its own inspection; and the questions and concerns raised by the FDA were the same questions and concerns that Alliance had raised with Hygia. *Id.* Comas also told Sadler that he believed that Alliance had contacted the FDA with the expectation that the FDA would conduct an investigation, that he believed Alliance was manipulating the FDA toward its own ends, and that providing him with the Alliance Report would allow Hygia to initiate litigation against Alliance for breach of the non-disclosure agreement. *Id.*

Sadler reviewed the Alliance Report and determined that the agency should withhold it as a confidential trade complaint. *Id.* at ¶ 7. In a letter dated September 15, 2006, the FDA denied the remainder of Hygia's request for the two reports. Comas Decl. at ¶ 9, Attach. 6; Sadler Decl. at ¶ 7. With respect to the Alliance Report, the FDA cited FOIA Exemptions 7(C) and 7(D) as grounds for its decision to withhold the document. Comas Decl. at ¶ 9, Attach. 6 at p. 1.

On October 18, 2006, Hygia filed an administrative appeal of the FDA's decision with DHHS. Comas Decl at ¶ 10, Attach. 7. By a letter dated January 10, 2007, DHHS notified Hygia that some additional information in the Turtil Report should have been made available. Comas Decl. at ¶ 12, Attach. 9. However, DHHS determined that the entirety of the Alliance Report should be withheld. *Id.* With respect to the Alliance Report, DHHS stated that the report was provided to the FDA "under an express promise of confidentiality or under circumstances from which an assurance of confidentiality could reasonably be inferred." *Id.* However, DHHS explained that because the FDA inadvertently revealed the source of the document, "we must now protect the entire substance of the [Alliance Report]." *Id.* DHHS also asserted Exemption 7 (C) and 7(D) "permit such withholdings." *Id.*

After Hygia filed the administrative appeal, Hygia sued the FDA under FOIA seeking disclosure of the redacted portions of the Turtil Report and of the Alliance Report. After the complaint was filed in this case, the FDA changed its position regarding the Turtil Report and it released the document in full to Hygia. Comas Decl. at ¶ 13.

ANALYSIS

I. The FDA's motion for leave to filed the supplemental declaration of Frederick D. Sadler

The FDA has requested leave to file a supplemental declaration of Frederick J. Sadler (doc. 21). In the supplemental declaration, Sadler states that the manner in which the trip report was written would permit Hygia to identify the employees

named in the trip report or that it would allow them to "narrow the field of likely individuals" that are named in the Alliance Report. Supplemental Sadler Decl. at ¶ 4. Further, in the declaration Sadler's states that in his experience, Hygia could look at the trip report and link its contents to one or two individuals. *Id.* The court finds that Sadler's declaration is based on speculation rather than personal knowledge, as required by Rule 56(e) of the Federal Rules of Civil Procedure. Therefore, the court finds that the FDA's motion for leave to filed the supplemental declaration of Frederick J. Sadler is due to be **DENIED**.

II. The Cross Motions for Summary Judgment

FOIA requires government agencies to make records available to any person, 5 U.S.C. § 552(a)(3)(A), unless the records fall within one of the nine statutory exemptions set out in 5 U.S.C. § 552(b)(1)-(9). Because the government bears the burden of demonstrating that it has properly withheld requested records, *See* 5 U.S.C. § 552(a)(4)(B), when moving for summary judgment, Hygia is only required to "point out to the district court ... that there is an absence of evidence to support the non-moving party's case." *Fitzpatrick v. City of Atlanta*, 2 F.3d 1112, 1115 (11th Cir. 1993) (quoting *U.S. v. Four Parcels of Real Property*, 941 F.2d 1428, 1437-38 (11th Cir. 1991)). In its motion for summary judgment, Hygia carried its initial burden of simply "pointing out" to the court that there is an absence of evidence to support the FDA's decision to withhold the Alliance Report.

In response to Hygia's motion for summary judgment, the FDA filed a motion for summary judgment. The question with respect to the FDA's motion is whether

the FDA can "show affirmatively the absence of a genuine issue of material fact." *Fitzpatrick*, 2 F.3d at 1115. If it can do so, summary judgment should be granted in favor of the FDA and Hygia's denied. However, if the FDA fails to demonstrate that a FOIA exemption applies, even under its version of the facts, the FDA's motion for summary judgment should be denied and Hygia's should be granted.

The purpose of FOIA is "to provide public access to most forms of government records. " *L & C Marine Transport Ltd. v. United States* , 740 F.2d 919, 922 (11th Cir. 1984). *See also Office of the Capital Collateral Counsel v. Dep't. of Justice*, 331 F.3d 799, 802 (11th Cir. 2003) ("The purpose of FOIA is to encourage public disclosure of information so citizens may understand what their government is doing."); *Arenberg v. Drug Enforcement Admin.*, 849 F.2d 579, 580 (11th Cir. 1988) ("FOIA is based on a policy of broad release of Government documents."). "In order to effectuate the Act's policy in favor of disclosure ... all FOIA exemptions are to be narrowly construed." *L & C Marine Transport*, 740 F.2d at 922.

The FDA asserts that the Alliance Report should be withheld under FOIA Exemptions 7(C) and 7(D). Sadler Decl. at ¶ 9-11. These exemptions were created to prevent disclosure of "records or information compiled for law enforcement purposes." 5 U.S.C. § 552(b)(7). Hygia does not dispute that the Alliance Report was *used* by the FDA for a law enforcement purpose. Pl.'s Opp's to Def.'s Mot. for Summ. J. at p. 4, n. 1. However, the FDA has the burden of proving that the Alliance Report was *compiled* for law enforcement purposes. *See* 5 U.S.C. § 552(a)(4)(B).

The FDA admits that the Alliance Report is an internal Alliance memorandum

from one Alliance employee to another that sets out Alliance's observations and concerns about Hygia's quality systems. Spears Decl. at ¶ 9. Although the Alliance Report may have been used by the FDA for law enforcement purposes, it was not *compiled* for law enforcement purposes. In fact, the evidence demonstrates that the Alliance Report was not generated during an FDA investigation of Hygia, and the evidence demonstrates that FDA played absolutely no role in compiling the information included in the Alliance Report. *See Arenburg*, 849 F.2d at 581 (holding that records that were "generated through a criminal investigation" were records compiled for law enforcement purposes). In addition, after reviewing the Alliance Report *in camera*, the court finds the FDA has failed meet its burden of demonstrating that the Alliance Report was *compiled* for law enforcement purposes. Review of the report reveals that the Alliance report was, in fact, *compiled* by Alliance employees for use in determining whether Alliance should enter into a business relationship with Hygia. FOIA Exemptions are to be narrowly construed, and the Exemption 7 unambiguously states that it applies to document that are compiled for law enforcement purposes. *See American Bankers Ins. Group v. United States*, 408 F.3d 1328, 1332 (11th Cir. 2005) (holding that a court should apply the plain meaning of a statute when it is unambiguous). Applying the plain meaning of Exemption 7, the court finds that the FDA has failed to establish a genuine issue of material fact exists with respect to whether the Alliance Report was compiled for law enforcement purposes. Therefore, the court finds that the FDA's motion for summary judgment is due to be **DENIED** and that Hygia's motion for summary judgment is

due to be **GRANTED**, which shall be done by separate order.

DONE and **ORDERED** this the 21st day of March 2007.

INGE PRYTZ JOHNSON
U.S. DISTRICT JUDGE